

# Validation and Reliability of Reflux Symptoms Score-12 in Bahasa Malaysia

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## ABSTRACT

**Introduction:** Laryngopharyngeal reflux is a prevalent disease. The combined multichannel intraluminal impedance and pH monitoring device is the “gold standard” to diagnose LPR but only available in certain centres. Primary care givers should be equipped with tools applicable everywhere to diagnose and monitor LPR efficiently such as the Reflux Symptoms Score 12 (RSS-12). This study was conducted to develop a Malay version of RSS-12 and to evaluate validity, consistency and reliability of this tool to be applied to the Malaysian population. **Methods:** The English RSS-12 was adapted into Bahasa Malaysia by an authorized translator. Content validation was done by 3 expert panels. Face validation performed using the questionnaire rated by 10 respondents from our clinic. A pilot study involving 30 patients was then conducted to determine the feasibility of the study. **Results:** The item-level content validity index (I-CVI) for all items was 1.0, the scale-level content validity index (S-CVI/Ave) was 1. The item-level face validity index (I-FVI) for all items was 0.95 -1.00 and scale-level face validity index based on the average method (S-FVI/Ave) was 0.99. Both indices of content validity and face validity achieved satisfactory level. For internal consistency, the Cronbach alpha for 3 domains in the MRSS-12 ranged between 0.891-0.928 which showed high reliability. **Conclusion:** M RSS-12 is practical, valid and reliable to be used among Malaysian population.

## INTRODUCTION

The term laryngopharyngeal reflux (LPR) first appeared in the world literature 4 decades ago [1]. Initially LPR was defined as retrograde flow of stomach contents into the larynx and pharynx causing injury to the upper aerodigestive tract mucosa [2]. This definition did not explain the effects of LPR on the ears and nose. Therefore, LPR is now defined as an inflammatory condition of the upper aerodigestive tract tissues related to the direct and indirect effect of gastric or duodenal content reflux, inducing morphological changes in the upper aerodigestive tract [3].

The estimated prevalence of LPR ranges between 5 to 30% of the general population depending on geographical, diet and lifestyle habits variations [4]. Approximately 10% to 30% of individuals seeking care at an otolaryngology practice exhibit symptoms or findings associated with LPR and 50% of those

with laryngeal and voice disorders have LPR [5]. This condition has significant impact on patient's quality of life, affecting their daily activities, voice impairment thus affecting social communications and psychological wellbeing [6].

Unfortunately, there is no pathognomonic sign or symptom for LPR. The various non-specific symptoms such as globus pharyngeus, hoarseness, chronic cough, dysphagia and postnasal drip can occur in other pathologies such as upper respiratory tract infections, rhinosinusitis or voice abuse. In addition, interindividual differences in the laryngopharyngeal mucosa sensitivity may be one of the most important factors that contribute to the differences in LPR clinical presentations [4]. The combined multichannel intraluminal impedance & pH (MII/pH) monitoring is currently the "gold standard" diagnostic tool for LPR [7]. However, there is still no consensus on standardization of diagnostic criteria for the MII/pH monitor [8]. In Malaysia the MII/pH exists in certain hospitals. Patients will have to pay RM200 to undergo this invasive uncomfortable diagnostic investigation.

In 2002, Belafsky et al developed a tool that can be applied anywhere by primary practitioners, the Reflux Symptoms Index (RSI) [9]. It is a 9-item patient reported outcome established to stratify the otorhinolaryngology symptoms associated with reflux. It is a useful tool but only addresses the severity of the patient's symptoms severity. It does not include how LPR symptoms affect patients' quality of life and some of the prevalent LPR symptoms such as throat pain, odynophagia, halitosis, regurgitation, and nausea were not included.

Due to the limitations of RSI, the Reflux Symptoms Score (RSS) was developed [10]. The RSS is a self-administered 22-item patient reported outcome not only used to diagnose and monitor LPR, but it also includes how LPR-related symptoms impacts patients' quality of life. The RSS exhibits high reliability and outstanding validity based on established criteria [10]. The original RSS however is lengthy and less practical in clinical applications. Subsequently a much simpler version, the Reflux Symptom Score-12 (RSS-12) was developed [11].

Malaysia is unique in the sense it is a multiracial country that encourage each ethnicity to practice their own language, tradition, and culture. There are Malay-medium schools and vernacular schools. However, Bahasa Malaysia is the national language and taught in all schools throughout our country. This study was done to develop a Malay version of RSS-12, evaluating its validity, consistency, and reliability among Malaysian population. This validated new version of RSS-12 will undoubtedly provide benefit to the Malaysian population in the diagnosis and surveillance of LPR, especially in primary care settings.

## **MATERIALS AND METHODS**

In this study, participants were voluntarily recruited from outpatients of our centre, Otorhinolaryngology Clinic of Hospital Al-Sultan Abdullah, from 4th August 2022 till 31st December 2022. Adult patients between ages 18 to 60 years old who agreed to participate in this research and fulfilled the LPR criterion (RSS-12 more than 11 with 1 or more oral/oropharyngeal sign) were recruited. Patients that were not willing to participate in the study or had other confounding factors such as acute upper respiratory tract infection, history of mechanical or chemical injury to the neck, neurological causes of dysphonia/dysphagia, presbycusis, esophageal or hypopharyngeal cancer and those contraindicated for Proton Pump Inhibitors (PPI) were excluded from the research. This study was approved by UiTM Research Ethics Committee (Reference number: REC/08/2022 (ST/MR/168). All participants involved signed an informed consent form before answering the questionnaires.

### **Double Blinded Translation**

The original English version of RSS-12 has been adapted into Bahasa Malaysia version Reflux Symptom Score 12 (M-RSS 12). Double blinded translation was conducted. The original English version was translated to Bahasa Malaysia by an authorized translator and subsequently the Bahasa Malaysia RSS-12 version was translated to English by another translator, without referring to the original English version of RSS-12.

## Content Validity

The preliminary M-RSS 12 underwent content validation. Three expert panels from three other universities rated each item's degree of relevance based on the Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, and 4 = highly relevant). Amendments were done based on the recommendations given. The scores from the experts were used to calculate the content validity index using two indices, the item-level content validity indices (I-CVI) and scale-level content validity indices based on the average method (S-CVI/Ave).

## Face Validity

Recruitment of 10 respondents from our centre who fulfilled the inclusion exclusion criteria was done and these respondents were not involved in our subsequent field study. They were asked to complete the amended M-RSS-12 in order to measure their clarity and comprehension regarding the translated questionnaire. Face Validity was measured using Face Validity Indices which are item-level face validity indices (I-FVI) and scale-level face validity indices based on the average method (S-FVI/Ave). Construct Validity (Exploratory Factor Analysis) was not carried out because of small sample size.

## Field Study

Subsequently, a field study was conducted involving 30 patients from our centre. The mean age was 48.77 and mean BMI was found to be 27.09 kg/cm<sup>2</sup>. The sociodemographic data is demonstrated in Table 1. They were given both M-RSS-12 and the validated Bahasa Malaysia Reflux Symptoms Index (M-RSI) [12]. Duration to complete M-RSS 12 ranged between 20-30 minutes with no difficulties reported. Correlation between M-RSS-12 and M-RSI score was calculated using Pearson correlation and scatter plot for distribution. Reliability analysis was done to determine the internal consistency by using Cronbach Alpha upon the three domains of the M-RSS-12 which is Severity Domain, Frequency Domain and Quality of Life Domain.

**Table 1** Sociodemographic of the respondents

Variables	Frequency, n (%)	Range
Age (years)	Mean = 48.77 (15.23)	Range = 25 - 75
Sex:		
Male	11 (36.7)	
Female	19 (63.3)	
Ethnicity:		
Malays	30 (100)	
Non-Malays	0 (0)	
Religion:		
Islam	30 (100)	
Others	0 (0)	
Smoking status:		
Smoker	0 (0)	
Non smoker	30 (100)	
Body mass index (BMI) (kg/m <sup>2</sup> )	Mean = 27.09 (4.62)	Range = 18.99 - 36.33

## RESULTS

### Content Validation

The questionnaire was refined based on recommendations by the panel to improve cultural understandings and prevent confusion to the respondents. The content validity indices calculations included I-CVI for all items were 1.0 with S-CVI/Ave 1. The CVI scores met a satisfactory level thus the scale of study instruments achieved a satisfactory level of content validity.

### Face Validation

Pertaining to the revised M-RSS-12 questionnaire answered by the 10 respondents, the face validity indices were as stated. I-FVI for all items ranged from 0.95 till 1.00, S-FVI/Ave was 0.99. The FVI scores met a satisfactory level subsequently the scale of study instruments achieved a satisfactory level of response validity.

### Field Study

The minimum score for M-RSS-12 was 0.00, with maximum score of 200.00 (Mean score 41.5667, Standard deviation 46.87304). The minimum score for M-RSI was 0.00 with maximum score of 35.00 (Mean score 12.3, Standard deviation 9.82309). Quality of life score for M-RSS-12 had a minimum score is 0.00, maximum score 55.00 (Mean score 15.6333, Standard deviation 14.64872). Scores for severity domain in M-RSS-12 is shown in Table 2. Correlation between similar items in M-RSS-12 and M-RSI, calculated using Pearson correlation and P value are shown in Table 3. Scatter plot of distribution of total score of M-RSS-12 and M-RSI shown in Figure 1, whereby it shows a positive correlation. For the internal consistency, Cronbach alpha of all three domains in M-RSS 12, severity, frequency and quality of life domains were calculated and all three domains ranged 0.891 till 0.928 which showed high reliability, as shown in Table 4.

**Table 2** Mean Scores for Severity Domain in M-RSS-12

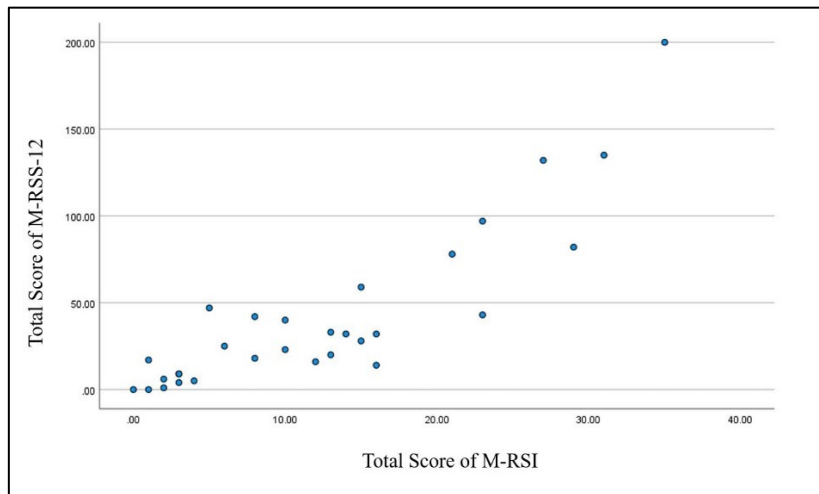
	Total respondents	Minimum	Maximum	Mean	Standard deviation
Suara serak atau ada masalah suara	30	0.00	5.00	1.3000	1.36836
Sakit tekak atau sakit semasa menelan	30	0.00	3.00	0.9667	1.12903
Kesukaran menelan (pil, cecair atau makanan pejal)	30	0.00	3.00	0.7000	0.98786
Membuang kahak untuk membersihkan tekak (bukan batuk)	30	0.00	5.00	1.3333	1.60459
Berasa sesuatu tersekat di kerongkong	30	0.00	5.00	1.8333	1.55549
Kahak berlebihan di tekak dan/atau hidung berair	30	0.00	5.00	1.4000	1.58875

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Nafas berbau	30	0.00	5.00	0.9667	1.42595
Pedih ulu hati, aliran balik asid perut, regurgitasi (muntah), sendawa, dan loya	30	0.00	4.00	1.6333	1.35146
Sakit perut atau cirit-birit	30	0.00	4.00	0.7667	1.04000
Ketakcernaan (rasa tidak hadam), kembung perut dan/atau sebu	30	0.00	4.00	1.4000	1.19193
Batuk (bukan sekadar untuk membuang kahak)	30	0.00	4.00	1.2667	1.33735
Kesukaran bernafas, sesak nafas dan nafas berbunyi	30	0.00	5.00	0.8000	1.56249

**Table 3** Correlation between similar items in M-RSS-12 and M-RSI

Items from M-RSI	Items from M-RSS-12	Pearson correlation, r	P value
Serak atau masalah suara	Suara serak	0.846	<0.001
Berdehem	Membuang kahak untuk membersihkan tekak	0.670	<0.001
Kahak berlebihan dalam tekak	Kahak berlebihan di dalam tekak	0.808	<0.001
Susah menelan makanan	Kesukaran menelan	0.733	<0.001
Susah bernafas	Kesukaran bernafas	0.921	<0.001
Batuk selepas makan	Batuk (bukan sekadar untuk membuang kahak)	0.718	<0.001
Rasa seperti sesuatu melekat	Berasa sesuatu tersekat di kerongkong	0.869	<0.001
Pedih ulu hati	Pedih ulu hati, merasa aliran asid	0.885	<0.001



**Figure 1** Scatter Plot for Total M-RSS and M-RSI

**Table 4** Cronbach Alpha of all three domains of M-RSS-12

Domain	Total Number of items	Cronbach Alpha
Severity Domain	12	0.906
Frequency Domain	12	0.891
Quality of Life Domain	12	0.928

## DISCUSSION

Symptoms of LPR lack specificity, making it challenging to diagnose. The “gold standard” method to diagnose LPR is via combined multichannel intraluminal impedance & pH (MII/pH). The reported sensitivity and specificity of the MII/pH monitor in diagnosing cough related to reflux was reported to be 92.6% and 63.6% [13]. The sensitivity and specificity to diagnose LPR objectively only reached 100% by combining multi-time point salivary pepsin testing (MTPSPT) and hypopharyngeal-oesophageal multichannel intraluminal impedance-pH monitoring (HEMII-pH) [14]. In Malaysia these invasive diagnostic instruments are expensive, not readily available in all centres and inconvenient. Based on an international survey, most otolaryngologists prefer to refer patients to the gastroenterologist rather than subject them to MII/pH due to patient inconvenience, the cost, the inability to interpret results, which leads to a lack of meaningfulness [15].

LPR is a highly prevalent disease worldwide and influenced by a variety of factors such as dietary habits, dental hygiene, stress, age and other comorbidities [16]. In addition, LPR has been found not only to cause physical pathologies leading to voice disorders, middle ear effusion [17] and recalcitrant rhinosinusitis [18] but also the cause of insomnia [19] that may lead to additional stress and depression subsequently worsening LPR, creating a vicious cycle. These are among the reasons that primary care givers play a vital role in LPR. The use of Patient-Related Outcome Measures (PROMs) and standardized clinical assessment instruments can undoubtedly help in diagnosing and monitoring the course of a disease [3]. The most frequently used for LPR for the past 4 decades is the RSI. An RSI of more than 13 would indicate a patient to have LPR. Patients with LPR show an improvement of RSI score after 2 months of intensive PPI treatment [9]. However, the sensitivity of the RSI was found to be 48.6% with a specificity of 82.5% [20]. An RSS 12 of more than 11 is very suggestive of LPR with a sensitivity of 94.5% and a specificity of 86.2% [11]. In addition, reassessment of LPR symptoms can be done within 1 month of PPI treatment using the RSS 12 [11]. Therefore, we chose to translate the RSS 12 to help our primary caregivers

apply the tool for the benefit of local population enabling better diagnosis, monitor response to treatment more regularly, as the RSS 12 scores can reveal monthly differences allowing recognition of red flags faster and referrals can be made earlier to either the otolaryngologist or gastroenterologist [16]. Our primary care colleagues are also very important in emphasizing compliance of diet and lifestyle changes, reminding patients of the long-term side effects of PPI, and ensuring PPI is taken before meals, as it is common for patients to assume all medications should be taken after meals.

Based on our research the M-RSS12 could be easily understood and answered by the general population in a short duration of time. The M-RSS 12 achieved satisfactory levels for content and response validity. There was positive correlation between M-RSS-12 and the validated M-RSI. The internal consistency was high for all three domains of our M-RSS 12 ranging between 0.891 to 0.928, at par with the RSS 12 translated into the Persian [21], Arabic [22] and Chinese [23] languages ranging between 0.72 to 0.878.

Challenges in this study include a small sample size and the inability to conduct objective investigations to confirm the diagnosis of LPR that occurred due to either patients are reluctant to undergo invasive procedures or the associated additional cost. We propose multicentre research in the future to address these limitations in order to improve sample size and overall results.

## **CONCLUSION**

The M-RSS 12 is a valid PROM that can be easily applied anywhere throughout the country and will definitely be of benefit to the Malaysian population. In addition, it can also be used in the future as a cross-cultural comparison that may improve our understanding of LPR and subsequently improve the quality of health care for these patients.

## **CONFLICT OF INTEREST**

The authors agree that this research was conducted in the absence of any self-benefits, commercial or financial conflicts and declare the absence of conflicting interests.

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## **AUTHORS' CONTRIBUTIONS**

Masaany Mansor conceived the ideas of the study. All authors conducted a meeting for the study designs and planning. Nesha Rajendram, Noor Shairah Mat Barhan, and Muhamad Ariff Sobani designed the study proposal. Nesha Rajendram presented the proposal of the study to the ethics committee. Masaany Mansor, Muhamad Ariff Sobani, Nesha Rajendram, and Noor Shairah Mat Barhan carried out the implementation of the study and collected the data. Nik Nairan Abdullah processed the study data, worked out the numerical calculations, and produced the results. Muhamad Ariff Sobani draft out the manuscript. Masaany Mansor reviewed and revised the manuscripts. Overall, Masaany Mansor supervised the progress of the study. All authors agree to be accountable for the study.

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